

Patent
09/785,243

REMARKS

Claims 7 and 11 are pending. Claim 7 is independent.

Section 112, first paragraph rejection

Claim 11 was rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement. The Action repeats the previous statement that "the specification does not adequately disclose a blood flow passageway through the partial helical shape as recited in the claims".

Applicants have amended the specification herein to include a specific recitation of the "blood flow passageway through the partial helical shape" as recited in Claim 11.

As noted in MPEP 2163.02, "an objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed'....an Applicant must convey with reasonable clarity to those skilled in the art that...he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed". This section continues, "the subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement". In fact, possession may be shown by a clear depiction of the invention in detailed drawings which will permit a person skilled in the art to clearly recognize that the Applicant had possession of the claimed invention. As noted in MPEP 2163.07(a), the application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.

The Examiner is respectfully directed at least to Figures 2 and 6, which *inherently illustrates*, to one skilled in the art, a "blood flow passageway" as claimed. This is believed to clearly show that Applicant was in possession of the invention when the application was filed. Reconsideration and withdrawal of the Section 112, first paragraph rejection are respectfully requested.

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Section 103(a) rejection

Independent Claim 7 was rejected under 35 USC 103(a) as being unpatentable US Patent 5,624,392 (Saab) in view of newly-cited US Patent 5,992,158 (Goddard et al.).

Specifically, the rejection takes the position that "Saab teaches all of the limitations of the claims" *except the supply lumen being insulated*. The Action then relies upon Goddard as teaching that it is known to "insulate the supply lumen (see column 8, line 49) to isolate the fluid from ambient conditions". The Action concludes that it would be obvious to "insulate the supply lumen of Saab to isolate the fluid from ambient conditions".

The rejection is respectfully traversed and reconsideration is requested.

Independent Claim 7 is directed to a cooling apparatus that includes a circulating unit adapted for chilling and circulating a fluid, a flexible elongated catheter and a flexible tubular outer catheter body on the catheter. A flexible, insulated, supply tube is located within the outer catheter body, a proximal end of a central lumen of the supply tube being connected in fluid flow communication with an outlet of the circulating unit. A return lumen is located within the outer catheter body, and substantially surrounds the fluid supply tube, a proximal end of the return lumen being connected in fluid flow communication with an inlet of the circulating unit. A flexible heat transfer element is mounted to a distal end of the outer catheter body and has a partially helical shape to increase the surface area available for heat transfer. The fluid supply tube comprises a wall having insulating properties to reduce heat transfer from said return lumen to said central lumen of said fluid supply tube.

Again, the structure recited in independent Claim 7 acts to "reduce heat transfer from the return lumen (that substantially surrounds the fluid supply tube) to the central lumen of said fluid supply tube" – as admitted in the Action, this element is not taught or suggested by Saab's alleged teaching of "preventing cooling of tissue in close proximity to the device" by having "sleeves 14 and 20 contain a heating fluid".

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In addition however, Goddard also fails to provide such a teaching. Fig. 3b of Goddard, and col. 8, lines 46-51, illustrate a cryosurgical probe tip in which insulated supply and exhaust passages (220, 230, respectively) are relatively thermally isolated from ambient conditions. However, Goddard does not teach or suggest that the supply tube has insulating properties to “reduce heat transfer from the exhaust tube” to the supply tube. Rather, as noted at col. 8, lines 1-4 (and illustrated in Fig. 3b), Goddard relies upon “vacuum chamber 210 [to] provide a degree of heat insulation between the cryogenic fluid passing inside the shaft 55 and the bodily tissue in contact with the shaft”. At lines 47-51 of col. 8, Goddard simply notes that at the ‘boiling region’ of the tip the cryogenic liquid “is in close thermal contact with tissue surrounding the tip, which contrasts with the insulated supply and exhaust passages 220, 230, where the liquid is relatively thermally isolated from ambient conditions”. The liquid is “thermally isolated” at “other than the boiling region” not due to the supply passage being insulated from the exhaust passage, but due to the vacuum chamber 210.

In fact, Goddard even specifically states at col. 8, lines 9-11 that “the returning exhaust fluid along the exhaust passageway 230 can help to keep the incoming fluid cool”.

For at least the foregoing reason, Applicant respectfully submits that Goddard fails to provide any teaching or suggestion of the element acknowledged to be not shown in Saab, and independent Claim 7 is therefore believed patentable over the teachings of Saab and Goddard and the rejection should be withdrawn.

Dependent Claim 11 is believed to be clearly patentable for all of the reasons indicated above with respect to Claim 7, from which it depends, and even further distinguishes over the cited references by reciting additional limitations.

Double Patenting Rejection

Independent Claim 7 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 12 of US Patent 6,231,595.

In order to overcome this rejection, Applicant shall file a terminal disclaimer at such time when the application is otherwise in condition for allowance.

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Since the Applicant has fully responded to each rejection set out in the Office Action, it is respectfully submitted that in regard to the above remarks that the pending application is patentable over the art of record and prompt review and issuance is accordingly requested. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicant's undersigned attorney at (908) 518-7700 in order that any outstanding issues be resolved.

Respectfully submitted,



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